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NOTICE OF ALLOWANCE AND FEE(S) DUE

52196

7590

07/06/2009

MEDTRONIC

Attn: Noreen Johnson - IP Legal Department
2600 Sofamor Danek Drive
MEMPHIS, TN 38132

EXAMINER

STEWART, ALVIN J

ART UNIT

PAPER NUMBER

3774

DATE MAILED: 07/06/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10763,719	01/23/2004	Thomas Zdeblick	MSDI-200/PC261.21	7326

TITLE OF INVENTION: METHODS AND INSTRUMENTS FOR INTERBODY FUSION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	10/06/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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 or Fax **(571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

52156 7590 07/06/2009

MEDTRONIC
 Attn: Noreen Johnson - IP Legal Department
 2600 Sofamor Danek Drive
 MEMPHIS, TN 38132

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10763.719 01/23/2004

Thomas Zdeblek

MSDI-200/PC261.21

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TITLE OF INVENTION: METHODS AND INSTRUMENTS FOR INTERBODY FUSION

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nonprovisional	NO	\$1510	\$300	\$0	\$1810	10/06/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
STEWART, ALVIN J	3774	623-017110

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a **Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
 (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY AND STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____
 Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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STEWART, ALVIN J

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2600 Sofamor Danck Drive
MEMPHIS, TN 38132

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.

10/763,719

Examiner

Alvin J. Stewart

Applicant(s)

ZDEBLICK ET AL.

Art Unit

3774

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed 3/16/09 and telephonic interview made 06/16/09.
2. ☒ The allowed claim(s) is/are 15-19, 21-23, 39-43, 45, 46, 50-52, 65, 67, 71 and 73 (renumbered as 1-22).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Brad A. Shepers on 06/16/09.

The application has been amended as follows:

16. A distraction device for distracting the disc space between adjacent vertebrae, comprising:

an elongated stem having a height corresponding to a desired height of distraction for the disc space, said stem having a first end and a second end defining a longitudinal axis therebetween and a length along said axis that is sized to be maintained within the disc space when said elongated stem is driven into the disc space; and

a flange at said first end projecting outward from said longitudinal axis of said stem, said flange having a bone contacting face for contacting at least one of the vertebrae when said stem is driven into the disc space and for transmitting a reduction force to the vertebra upon application of an external force to the distraction device; and

wherein said elongated stem defines a bore extending between said first end and said second end, said bore including a keyed bore adjacent said second end, said keyed bore having a non-circular configuration for receiving a complementary-shaped portion of a tool therethrough, and wherein said bore includes a threaded bore adjacent said first end for receiving a threaded portion of a tool therein.

18. The distraction device according to claim 23, wherein ~~said elongated stem has opposite top and bottom portions~~, said top and bottom ~~portions~~ surfaces having each comprise a bone engaging surface configured to resist expulsion of said elongated stem from the disc space.

19. The distraction device according to claim 18, wherein said bone engaging surface of ~~said top and bottom portions~~ includes a plurality of ridges defined thereon.

20. (Cancelled)

22. A distraction device for distracting the disc space between adjacent vertebrae, comprising:

an elongated stem having a height corresponding to a desired height of distraction for the disc space, said stem having a first end and a second end defining a longitudinal axis therebetween and a length along said axis that is sized to be maintained within the disc space when said elongated stem is driven into the disc space; and

a flange at said first end projecting outward from said longitudinal axis of said stem, said flange having a bone contacting face for contacting at least one of the vertebrae when said stem is driven into the disc space and for transmitting a reduction force to the vertebra upon application of an external force to the distraction device, wherein said flange is fan shaped including concave side edges and is substantially perpendicular to said longitudinal axis of said elongated stem; and

an elongated driver shaft extending generally along said longitudinal axis and sized to extend outside of the disc space for transmission of said external force to the distraction device.

23. ~~A distraction device for distracting the disc space between adjacent vertebrae, comprising:-~~

~~an elongated stem having a height corresponding to a desired height of distraction for the disc space, said stem having a first end and a second end defining a longitudinal axis therebetween and a length along said axis that is sized to be maintained within the disc space when said elongated stem is driven into the disc space; and~~

~~a flange at said first end projecting outward from said longitudinal axis of said stem, said flange having a bone contacting face for contacting at least one of the vertebrae when said stem is driven into the disc space and for transmitting a reduction force to the vertebra upon application of an external force to the distraction device; and~~ The distraction device of claim 22,

wherein said elongated stem includes opposite top and bottom surfaces configured to contact a superior and an inferior vertebra, respectively;

said flange projects from said stem in a direction toward the superior vertebra; and
the device includes a stop face at said first end of said stem projecting in a direction toward the inferior vertebra; and

~~an elongated driver shaft extending generally along said longitudinal axis and sized to extend outside of the disc space for transmission of said external force to the distraction device.~~

24.-38. (Cancelled)

39. The ~~distraction device method~~ of claim ~~73~~ 67, wherein ~~each of said stem portion includes~~ top and bottom bone engaging surfaces ~~are~~ configured to resist expulsion of said stem portion from the intervertebral space.

40. The ~~distraction device method~~ of claim ~~73~~ 39, wherein said ~~opposite~~ top and bottom bone engaging surfaces each define a plurality of ridges configured to resist expulsion of said stem portion from the intervertebral space.

41. A distraction device for distracting an intervertebral space between adjacent vertebrae, comprising:

a stem portion extending along a longitudinal axis and adapted for insertion within the intervertebral space, said stem portion having a first end, a second end, and upper and lower surfaces defining a height corresponding to a select distracted height of the intervertebral space and including side portions, each of said side portions defining a side surface having a concave curvature extending between said upper and lower surfaces; and

a transverse flange portion at said first end projecting outward from said longitudinal axis of said stem portion and having a bone side contacting face adapted to engage one of the side of the adjacent vertebrae when said stem portion is inserted into the intervertebral space to transmit an axial force to said one of the adjacent vertebrae.

42. The distraction device of claim 41, wherein said flange portion includes concave side edges, each of said concave side edges being contiguous with a corresponding one of said concave side surfaces of said side portions.

43. A distraction device for distracting an intervertebral space between adjacent vertebrae, comprising:

a stem portion extending along a longitudinal axis and adapted for insertion within the intervertebral space, said stem portion having a height corresponding to a select distracted height of the intervertebral space; and

a transverse flange portion having a fan-shaped configuration including concave side edges and a bone contacting face adapted to engage one of the adjacent vertebrae when said stem portion is inserted into the intervertebral space to transmit an axial force to said one of the adjacent vertebrae; and

an elongated driver shaft extending generally along said axis and sized to extend outside of the intervertebral space for application of an external force to the distraction device to transmit said axial force to said one of the adjacent vertebrae.

45. The ~~distraction device method~~ of claim 46, wherein said transverse stop ~~element portion~~ is formed integral with said stem portion and together define a portion of said single-piece, monolithic structure.

46. The ~~distraction device method~~ of claim ~~73~~ 67, wherein said transverse flange portion is formed integral with said stem portion and together define a single-piece, monolithic structure.

50. A ~~distraction device for distracting an intervertebral space between adjacent vertebrae, comprising:~~

~~a stem portion extending along a longitudinal axis and adapted for insertion within the intervertebral space, said stem portion having a height corresponding to a select distracted height of the intervertebral space;~~

~~a transverse flange portion having a bone contacting face adapted to engage one of the~~

adjacent vertebrae when said stem portion is inserted into the intervertebral space to transmit an axial force to said one of the adjacent vertebrae; and

a transverse stop element arranged generally opposite said transverse flange portion relative to said longitudinal axis, said transverse stop element adapted to engage an opposite one of the adjacent vertebrae to limit insertion of said stem portion into the intervertebral space; and The distraction device of claim 41, further comprising: an elongated driver shaft extending generally along said axis and sized to extend outside of the intervertebral space for application of an external force to the distraction device to transmit said axial force to said one of the adjacent vertebrae, wherein said axial force comprises a reduction force to reduce a spondylolisthesis condition between the adjacent vertebrae, and

wherein said elongated driver shaft is threadedly engaged with said stem portion.

52. A distraction device for distracting an intervertebral space between adjacent vertebrae, comprising:

a stem portion extending along a longitudinal axis and adapted for insertion within the intervertebral space, said stem portion having a height corresponding to a select distracted height of the intervertebral space and including side portions, each of said side portions defining a concave surface; and

a transverse flange portion having a bone contacting face adapted to engage one of the adjacent vertebrae when said stem portion is inserted into the intervertebral space to transmit an axial force to said one of the adjacent vertebrae; and The distraction device of claim 41, wherein said stem portion is configured for selective engagement with a surgical instrument, one of said stem portion and said surgical instrument defining a passage, another of said stem portion and said surgical instrument defining a projection at least partially received within said passage to locate said surgical instrument relative to the adjacent vertebrae.

73. ~~A distraction device for distracting an intervertebral space between adjacent vertebrae, comprising:~~

~~a stem portion extending along a longitudinal axis and adapted for insertion within the intervertebral space, The method of claim 67, wherein said stem portion having has a height~~

corresponding to a select distracted height of the intervertebral space; and

~~a transverse flange portion having a bone contacting face adapted to engage one of the adjacent vertebrae when said stem portion is inserted into the intervertebral space to transmit an axial force to said one of the adjacent vertebrae; and~~

~~a transverse stop element arranged generally opposite said transverse flange portion relative to said longitudinal axis, said transverse stop element adapted to engage an opposite one of the adjacent vertebrae to limit insertion of said stem portion into the intervertebral space; and~~

~~an elongated driver shaft extending generally along said axis and sized to extend outside of the intervertebral space for application of an external force to the distraction device to transmit said axial force to said one of the adjacent vertebrae;~~

wherein said stem portion includes a rounded leading end portion to facilitate insertion of said stem portion into the intervertebral space and distraction of the adjacent vertebrae, said stem portion having opposite top and bottom bone engaging surfaces with said height of said stem portion defined between said opposite top and bottom bone engaging surfaces; and

wherein said rounded leading end portion of said stem portion defines a curvature extending along said height between said opposite top and bottom bone engaging surfaces to facilitate insertion of said stem portion into the intervertebral space and distraction of the adjacent vertebrae.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: After careful consideration of the Applicant's remarks the Examiner has found the independent claims are allowable. There is no evidence in the prior art of a distraction device comprising a stem portion having a longitudinal axis, the stem portion having a first and second ends and side portions, each of the side portion defining a side surface having concave curvature extending from an upper surface to a lower surface. A flange portion extending radially from the proximal end of

the stem portion and having a side contacting face capable of contacting a patient's adjacent side face vertebrae.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin J Stewart/
Primary Examiner, Art Unit 3774

06/19/09

Application/Control Number: 10/763,719
Art Unit: 3774

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